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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/431,469	11/01/1999	DAVID M. ARMISTEAD	VPI/95-09-DI	8756

7590 10/07/2003

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NEW YORK, NY 100201104

EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 10/07/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/431,469

Applicant(s)

ARMISTEAD ET AL.

Examiner

Marjorie A. Moran

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Producing a crystal of a molecule or molecular complex comprising only CnA/CnB is new matter. Original claims 6 and 16 recited a crystal and preparation of a crystal comprising all of CnA/CnB/FKBP12 and FK506. The originally filed specification, on page 27, discloses crystallization of a molecular comprising CnA/CnB/FKBP12 and FK506 after a digestion step. Page 30 of the originally filed specification discloses a binary complex of FKBP12 and FK506, to which calcineurin is added before a digestion step to produce a complex comprising all of CnA/CnB/FKBP12 and FK506. Similarly, the Examples on pages 31-36 disclose production of a complex comprising all of CnA/CnB/FKBP12 and FK506. Nowhere do the originally filed specification or claims recite or disclose a crystal, or production of a crystal of CnA/CnB in the absence of FKBP12 and FK506. For these reasons, claims 31-32 recite new matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19-30 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over HENDRY et al. (US 5,705,335).

Applicant's arguments filed 6/20/03 have been fully considered but they are not persuasive. In response to the argument that the claimed structure coordinates "impose a change on the processing steps in the claimed method", as set forth on page 8 of the response, it is noted that the coordinates themselves do not impose a change on the computer program utilized to perform the fitting operation. The program steps remain the same; i.e. the fitting operation and energy calculations may be performed on any set of data provided it is arranged in a format recognized by the program. In addition, the data itself is not changed or transformed by the program steps. The data is used for comparison (e.g. to other data representing a ligand), but is not actually transformed into a different data set. For these reasons, the rejection

of claims 19-25 is maintained and claims 26-30 are rejected. It is noted that claims 26-30 were inadvertently omitted from the rejection in the previous office action.

HENDRY teaches a method to evaluate the ability of a chemical compound to associate with another (the "degree of fit" of binding to a pharmacophore) wherein a ligand is docked (fitting operation) into a binding site, and the results evaluated (col. 7, lines 9-24). HENDRY also teaches "outputting" results of his fitting method (Figures 1-4). HENDRY further teaches that compounds identified using a computer modeling/docking algorithm may be synthesized (col. 10, lines 17-21) and evaluated for binding in *in vitro* assays (col. 10, line 40-col. 11, line 64). HENDRY further teaches molecular modeling and energy calculations to perform his fitting operations (col. 6, lines 25-42, col. 11, line 65-col. 12, line 11 and col. 13, lines 19-31), and teaches fitting through visual inspection of 3D images on a computer screen (Figure 6, col. 6, lines 44-52, and col. 7, lines 9-24), thereby making obvious all of the steps of the claimed methods. It is noted that the structure coordinates recited in the claims are nonfunctional descriptive material as they do not impose a change on the processing steps used in the claimed methods. Algorithms to fit or dock a molecular entity into a binding site of a molecule or molecular complex are known in the art, as set forth above. A method of using a known algorithm for its known purpose does not become nonobvious merely because new data is available for analysis. Nonfunctional descriptive material cannot render non-obvious an invention that would have otherwise been obvious. See *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983) and MPEP 2106. Applicant is also directed to the Trilateral Project WM4 Report on Comparative Study on Protein 3-Dimensional (3-D) Structure Related Claims at: [http://www.uspto.gov/web/tws/wm4/wm4\\_3d/report.htm](http://www.uspto.gov/web/tws/wm4/wm4_3d/report.htm)

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**Conclusion**

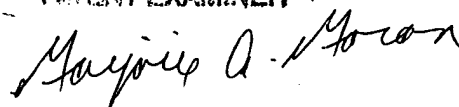
Claims 19-34 are rejected. Claims 31-32 appear to be free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN  
PATENT EXAMINER



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